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Title 21 Code of Federal Regulations

PART 1301 — REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

SECURITY REQUIREMENTS

§1301.71 Security requirements generally.

(a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in Secs. 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. Materials and construction which will provide a structural equivalent to the physical security controls set forth in Secs. 1301.72, 1301.73 and 1301.75 may be used in lieu of the materials and construction described in those sections.

(b) Substantial compliance with the standards set forth in Secs. 1301.72-1301.76 may be deemed sufficient by the Administrator after evaluation of the overall security system and needs of the applicant or registrant. In evaluating the overall security system of a registrant or applicant, the Administrator may consider any of the following factors as he may deem relevant to the need for strict compliance with security requirements:

- (1) The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.);
- (2) The type and form of controlled substances handled (e.g., bulk liquids or dosage units, usable powders or nonusable powders);
- (3) The quantity of controlled substances handled;
- (4) The location of the premises and the relationship such location bears on security needs;
- (5) The type of building construction comprising the facility and the general characteristics of the building or buildings;
- (6) The type of vault, safe, and secure enclosures or other storage system (e.g., automatic storage and retrieval system) used;
- (7) The type of closures on vaults, safes, and secure enclosures;
- (8) The adequacy of key control systems and/or combination lock control systems;
- (9) The adequacy of electric detection and alarm systems, if any including use of supervised transmittal lines and standby power sources;
- (10) The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;
- (11) The adequacy of supervision over employees having access to manufacturing and storage areas;
- (12) The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel;
- (13) The availability of local police protection or of the registrant's or applicant's security personnel;
- (14) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations; and (15) The applicability of the security requirements contained in all Federal, State, and local laws and regulations governing the management of waste.

(c) When physical security controls become inadequate as a result of a controlled substance being transferred to a different schedule, or as a result of a noncontrolled substance being listed on any schedule, or as a result of a significant increase in the quantity of controlled substances in the possession of the registrant during normal business operations, the physical security controls shall be expanded and extended accordingly. A registrant may adjust physical security controls within the requirements set forth in Secs. 1301.72-1301.76 when the need for such controls decreases as a result of a controlled substance being transferred to a different schedule, or as a result of a controlled substance being removed from control, or as a result of a significant decrease in the quantity of controlled substances in the possession of the registrant during normal business operations.

(d)Any registrant or applicant desiring to determine whether a proposed security system substantially complies with, or is the structural equivalent of, the requirements set forth in Sec. Sec. 1301.72-1301.76 may submit any plans, blueprints, sketches or other materials regarding the proposed security system either to the Special Agent in Charge in the region in which the system will be used, or to the Regulatory Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in Sec. 1321.01 of this chapter for the current mailing address.

(e) Physical security controls of locations registered under the Harrison Narcotic Act or the Narcotics Manufacturing Act of 1960 on April 30, 1971, shall be deemed to comply substantially with the standards set forth in Secs. 1301.72, 1301.73 and 1301.75. Any new facilities or work or storage areas constructed or utilized for controlled substances, which facilities or work or storage areas have not been previously approved by the Administration, shall not necessarily be deemed to comply substantially with the standards set forth in Secs. 1301.72, 1301.73 and 1301.75, notwithstanding that such facilities or work or storage areas have physical security controls similar to those previously approved by the Administration.

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(f) A collector shall not employ, as an agent or employee who has access to or influence over controlled substances acquired by collection, any person who has been convicted of any felony offense relating to controlled substances or who, at any time, had an application for registration with DEA denied, had a DEA registration revoked or suspended, or has surrendered a DEA registration for cause. For purposes of this subsection, "for cause" means in lieu of, or as a consequence of, any Federal or State administrative, civil, or criminal action resulting from an investigation of the individual's handling of controlled substances.

[36 FR 18729, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 46 FR 28841, May 29, 1981; 47 FR 41735, Sept. 22, 1982; 51 FR 5319, Feb. 13, 1986; 68 FR 41228, July 11, 2003; 75 FR 10677, Mar. 9, 2010; 79 FR 53561, Sept. 9, 2014]

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